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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,548	07/11/2003	Ashish Anilbhai Patel	G-33280P1	5169

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/618,548	Applicant(s) PATEL ET AL.	
	Examiner Raymond J Henley III	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 14-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10 and 14-21 is/are rejected.
- 7) ☒ Claim(s) 3, 16 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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CLAIMS 1-10 AND 14-21 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment filed July 2, 2004 has been received and entered into the application. Accordingly, claims 1 and 21 have been amended and claims 11-13 have been canceled.

Claim Objections

Claims 16 and 17 are objected to because of the following informality:

Claim 16 (and thus claim 17) depend from a canceled claim. Appropriate correction is required.

Claim 3 is objected to as depending from a rejected base claim, but is otherwise in condition for allowance for the reasons presented below.

Claim Rejection - 35 USC § 103

Claims 1, 2, 4-10 and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al. (U.S. Patent No. 4,743,450, cited by Applicants) in view of Vivilecchia et al. (U.S. Patent No. 6,300,361, cited by Applicants), Handbook of Pharmaceutical Excipients ("the Handbook", cited by the Examiner), Applicants' acknowledgment at page 4, third full paragraph – page 5, second full paragraph of the present specification and Remington's Pharmaceutical Sciences ("Remington's", cited by the Examiner), each of record, for the reasons of record as set forth in the previous Office action, as applied to claims 1-21.

Applicants' arguments have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

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In particular, applicants have argued at page 6 of their amendment that they have “unexpectedly determined that tablets prepared with an ACE inhibitor, such as quinapril, and a low-substituted hydroxypropyl cellulose exhibited greater stability as determined by the amount of by-products, quinaprilate and DKP, which were formed, as compared to tablets prepared without a low-substituted hydroxypropyl cellulose. Obviously, the lower the amount of by-products which are formed in a particular formulation, the more stable the formulation.”.

While the Examiner will agree that unexpected results have been demonstrated where the ACE inhibitor is quinapril (and thus the objection to claim 3 directed to quinapril), the rejection is deemed to remain proper because the claims are not limited to quinapril as the ACE inhibitor and thus not commensurate in scope with the evidence offered.

The Examiner would consider extending the probative value of the evidence offered if applicants can establish, through additional data or sound scientific reasoning, that the other claimed ACE inhibitors would be expected to behave in a similar manner as quinapril.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
Art Unit 1614

May 24, 2004